

STATEMENT BY REPRESENTATIVE DIANA DEGETTE
BEFORE THE
NATIONAL HUMAN RESEARCH PROTECTIONS ADVISORY COMMITTEE
ROCKVILLE, MARYLAND
TUESDAY, JULY 31, 2001

INTRODUCTION

THANK YOU. I AM PLEASED TO SHARE THESE MOMENTS WITH YOU.
KATE-LOUISE AND MARY FAITH BRIEFED ME ON YOUR EFFORTS. IT IS
EXCITING WORK, INDISPENSABLE TO THE NATIONAL INTEREST, AND I AM
PLEASED TO BE A SMALL PART OF YOUR DELIBERATIONS.

SCIENCE AND ETHICS

IN COLLEGE ONE OF MY PROFESSORS USED TO OFFER PITHY STATEMENTS
ABOUT SCIENCE. HE LOVED THIS ONE BY GALILEO: "SCIENCE ONLY
GROWS." I THINK MOST STUDENTS OF SCIENCE SEE IT AS A PROGRESSIVE
CONQUEST OF THE UNKNOWN. CERTAINLY, AT THE BEGINNING OF THE
20TH CENTURY, THE OPTIMISM OF DARWIN, FREUD, AND T.H. HUXLEY HAD
BEEN TRANSLATED INTO "THE" PARADIGM PICTURE OF SCIENCE. IN THAT
FIRST DECADE, H.G. WELLS, BERTRAND RUSSELL, AND WILLIAM OSLER
PERSUASIVELY ARGUED THAT SCIENCE AND PROGRESS WERE ONE.

AT THE DAWN OF THE 21ST CENTURY, IN OUR FIRST DECADE, OUR VISION OF SCIENCE HAS SOBERED. AFTER 100 YEARS OF ANYTHING BUT SOLITUDE, WE HAVE LEARNED TOO MUCH TO EVER BE UNQUESTIONABLY, FAITHFULLY OPTIMISTIC AGAIN. PROGRESS IN SCIENCE AND MEDICINE OFTEN COMES AT A PRICE, FORCING US INTO MORE AND MORE DIFFICULT DECISIONS, CONFRONTING US WITH ETHICAL PERPLEXITIES AND MORAL PARADOXES, TANTILIZING US WITH GREATER AND GREATER POSSIBILITIES FOR CHANGING THE WORLD.

BECAUSE WE KNOW MORE, WE ALSO REALIZE A GREATER MEASURE OF RESPONSIBILITY. WE NOW SEE POTENTIALS FOR MISUSE OR ABUSE THAT WERE BEYOND THE IMAGINATION OF VICTORIAN OPTIMISTS.

WE REMAIN FIRMLY CONVINCED THAT SCIENCE AND MEDICINE ARE THE TOOLS FOR A BETTER WORLD, IF THOSE TOOLS ARE USED PROPERLY, WITH VISION, COMPASSION, HUMANITY, AND HUMILITY. AS WE TRAVEL FARTHER INTO THIS CENTURY, OUR DISCOVERIES WILL OPEN UP GREATER AND GREATER OPPORTUNITIES FOR ADDRESSING DISEASE, DISABILITY, AND DEATH.

BUT GREATER KNOWLEDGE WILL ALSO PRESENT US WITH PROFOUND CHALLENGES ABOUT QUALITY OF LIFE, AGING, RESOURCE UTILIZATION AND MANAGEMENT, AND ABOUT LIFE ITSELF.

HOW WE ADDRESS THESE ISSUES WILL SAY MUCH ABOUT US AS PEOPLE, AS A CULTURE, AND AS A GLOBAL COMMUNITY.

WE HAVE TO RECOGNIZE THAT THE HEALTH OF RESEARCH SUBJECTS IS JUST AS IMPORTANT AS THE INTEGRITY OF THE DATA. BIOMEDICAL SCIENCE IS NO LONGER CONFINED TO THE LABORATORY. IT HAS SPREAD BEYOND THE WALLS OF ACADEMIA TO THE BUSINESS CAMPUS, GOVERNMENT FACILITIES, AND MANY OTHER SETTINGS, WITH EACH POTENTIALLY EMPLOYING VASTLY DIFFERENT METHODOLOGIES. WE CANNOT ASSUME THAT RESEARCH SUBJECTS ARE UNIFORMLY PROTECTED IN THIS WIDE RANGE OF SETTINGS.

OF COURSE, THIS RESEARCH IS IMPORTANT, AND I'M NOT SUGGESTING WE ABANDON VITAL AVENUES TO IMPROVED HEALTH. WE CANNOT CALLOUSLY TURN OUR BACKS ON THE REAL AND PRESSING NEEDS OF PEOPLE WITH DIABETES, ALZHEIMER'S DISEASE, PARKINSON'S DISEASE, CANCER, SPINAL CORD INJURIES, OR MANY OTHER HEALTH PROBLEMS. WE ALSO CANNOT UNLEASH SCIENCE WITHOUT CONCERN FOR THE ETHICAL AND POLITICAL DECISIONS THAT ACCOMPANY SUCH ADVANCES.

CONGRESS AND THE ADVISORY COMMITTEE

WE MUST FORGE CONSENSUS AROUND WORKABLE AND EFFECTIVE APPROACHES TO MEDICINE AND RESEARCH. THAT MAY BE THE GREATEST CHALLENGE OF ALL.

IN TRYING TO CRAFT A UNIFORM STANDARD, WE ARE LOOKING TO YOU AND TO OTHER ADVISORY COMMITTEES TO PROVIDE CLARITY, POLICY OPTIONS, AND ASSESSMENT OF THE IMPACT OF VARIOUS CHOICES. WE KNOW THESE ISSUES ARE MIND-BOGGLING. WE DO NOT NEED THE INHERENTLY COMPLEX TO BE TRIVIALIZED INTO ABSURD SIMPLICITIES. BUT WE DO NEED TO MAKE THE COMPLEX UNDERSTANDABLE.

THAT IS WHY YOUR WORK IS SO IMPORTANT. WITH EACH PASSING DAY, THIS ADVISORY COMMITTEE IS PUSHED INTO THE FOREFRONT OF THE DEBATE ON HUMAN SUBJECT RESEARCH. MEMBERS OF CONGRESS, THE ADMINISTRATION, AND THE AMERICAN PEOPLE NEED TO HEAR YOUR WISDOM, TO LEARN ABOUT YOUR EXPERIENCES, AND TO DISCUSS YOUR FINDINGS AND RECOMMENDATIONS. IN MY VIEW, THERE MAY BE NO MORE IMPORTANT, TIMELY, AND NECESSARY ADVISORY COMMITTEE IN OPERATION TODAY.

STANDARDS FOR RESEARCH

I WOULD LIKE TO COMMEND YOUR EXECUTIVE SECRETARY, DR. GREG KOSKI (AND THE EMINENT DR. STUART NIGHINGALE), FOR A RECENT ARTICLE IN THE *NEW ENGLAND JOURNAL OF MEDICINE*. THAT DISCUSSION WAS A VALUABLE ADDITION TO THE LITERATURE. I AGREE THAT THERE IS AN OBVIOUS NEED TO ESTABLISH INTERNATIONAL STANDARDS FOR THE ETHICAL AND SCIENTIFIC CONDUCT OF CLINICAL RESEARCH. I PARTICULARLY AGREED WITH THE CONCLUSION: "ALL RESEARCH INVOLVING HUMAN SUBJECTS (REQUIRES US TO UNDERSTAND THAT) ETHICS AND SCIENCE ARE NOT SEPARABLE..."

ALL RESEARCH MUST BE RESPECTFUL AND MUST DO NO HARM TO THE SUBJECTS. IN A COMPANION PIECE, DR. HAROLD SHAPIRO AND DR. ERIC MESLIN ARGUED THAT THE UNITED STATES SHOULD TAKE THE LEAD IN RESEARCH SUBJECT PROTECTION. IN FACT, THEY ARGUE THAT OUR STANDARDS SHOULD BE REPLICATED AROUND THE WORLD. THEY ASK THAT "ALL CLINICAL TRIALS CONDUCTED ABROAD SHOULD MEET ALL THE ETHICAL STANDARDS FOR TRIALS BASED IN THE UNITED STATES, INCLUDING PRIOR REVIEW AND APPROVAL BY ETHICS REVIEW COMMITTEES, THE MINIMIZATION OF RISK TO THE PARTICIPANTS, A FAVORABLE RISK-BENEFIT RATION, AND THE PROVISION OF INDIVIDUAL INFORMED CONSENT BY ALL COMPETENT ADULT PARTICIPANTS."

HUMAN RESEARCH SUBJECT PROTECTIONS ACT

IF THEY ARE RIGHT, THEN IT IS UP TO US TO SET A HIGH STANDARD IN PATIENT PROTECTION. SEVERAL YEARS AGO I BECAME PERSONALLY CONCERNED ABOUT THIS ISSUE AFTER READING ABOUT PATIENTS WHO DIED IN STUDIES NOT COVERED BY NIH GUIDELINES OR OTHER PROTECTIONS. THE TEMPORARY HALTING OF RESEARCH AT THE UNIVERSITY OF COLORADO HEALTH SCIENCES CENTER FURTHER HEIGHTEN MY INTEREST IN THIS ISSUE. AS A RESULT, I DEVELOPED LEGISLATION THAT I AM RE-INTRODUCING THIS YEAR AS THE "HUMAN RESEARCH SUBJECT PROTECTIONS ACT OF 2001." I AM A PRIME SPONSOR, WORKING VERY CLOSELY WITH REPRESENTATIVE JAMES GREENWOOD. THIS LEGISLATION IS THE FIRST COMPREHENSIVE IMPROVEMENT IN TWO DECADES OF REGULATIONS THAT GOVERN HUMAN RESEARCH. IT INCORPORATES MANY RECOMMENDATIONS OF THE GENERAL ACCOUNTING OFFICE AND THE HHS OFFICE OF INSPECTOR GENERAL.

AS YOU KNOW, THE NATIONAL BIOETHICS ADVISORY COMMISSION ARGUED THAT "NO PERSON IN THE UNITED STATES SHOULD BE ENROLLED IN RESEARCH WITHOUT THE TWIN PROTECTION OF INFORMED CONSENT BY AN AUTHORIZED PERSON AND INDEPENDENT REVIEW OF THE RISKS AND BENEFITS OF THAT RESEARCH." THAT IS A REASONABLE, MORALLY IMPERATIVE, EXPECTATION. YET, FEDERAL PROTECTIONS FOR

PERSONS SERVING AS RESEARCH SUBJECTS DO NOT YET EXTEND TO ALL AMERICANS. THIS LEGISLATION APPLIES THE COMMON RULE TO ALL RESEARCH REGARDLESS OF THE SOURCE OF FUNDING.

THIS LEGISLATION PROVIDES AUTHORITY FOR A SINGLE OVERSIGHT OFFICE FOR THE REGULATION OF HUMAN SUBJECT PROTECTIONS. IT IS COMPREHENSIVE, COVERING BOTH FEDERALLY FUNDED AND PRIVATE RESEARCH. UNLIKE THE CURRENT REGULATIONS, WHICH COVERS ONLY NIH AND FDA, ALL PUBLIC AND PRIVATE RESEARCH WOULD BE INCLUDED.

THE UPDATED BILL ADOPTS A NUMBER OF RECOMMENDATIONS MADE BY THE NATIONAL BIOETHICS ADVISORY COMMISSION AND OTHER GROUPS. THESE RECOMMENDATIONS INCLUDE ESTABLISHING REGULATORY OVERSIGHT THAT IS COMMENSURATE WITH THE LEVEL OF RESEARCH RISK, STRENGTHENING CONFLICT OF INTEREST PROVISIONS, TIGHTENING MONITORING REQUIREMENTS OF ONGOING RESEARCH PROJECTS, AND STRENGTHENING THE INSTITUTIONAL REVIEW BOARD SYSTEM

FOR EXAMPLE, IT WOULD IMPROVE THE EDUCATION AND TRAINING OF INVESTIGATORS AND INSTITUTIONAL REVIEW BOARD MEMBERS FOR HUMAN SUBJECT PROTECTIONS.

IT WOULD IMPROVE THE INFORMED CONSENT PROCESS. IN FACT, IT STATUTORILY REQUIRES THAT INFORMED CONSENT AND INDEPENDENT REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS BE OBTAINED.

AND IT WOULD EXPAND RESOURCES FOR INSTITUTIONAL REVIEW BOARDS TO THOROUGHLY AND APPROPRIATELY EXAMINE ALL HUMAN SUBJECT RESEARCH.

CONCLUSION

TODAY, CONGRESS WILL BE DISCUSSING CLONING AND STEM CELL RESEARCH. THESE DEBATES WILL BE AMONG THE MOST IMPORTANT IN THE HISTORY OF OUR INSTITUTION. THEY WILL LAY AN IMPORTANT FOUNDATION FOR DEBATES ON BIOETHICAL ISSUES IN THE YEARS AND DECADES AHEAD.

THESE DEBATES WILL BE INCOMPLETE UNLESS ACCOMPANIED BY DELIBERATIONS ON RESEARCH INVOLVING HUMAN SUBJECTS. WE CANNOT CREDIBLY TALK ABOUT IMPROVING HEALTH OR CURING ILLNESS UNLESS WE ALSO PROVIDE PROTECTION FOR HUMAN SUBJECTS IN BIOMEDICAL EXPERIMENTS.

SOMETIMES PROGRESS IN SCIENCE IS NOT MEASURED BY NEW DATA OR LANDMARK DISCOVERIES. IT MAY BE MEASURED BY THE RESPECT WE

SHOW PEOPLE AND THE ETHICAL POSTURE WE TAKE FOR THEIR PROTECTION. IF SCIENCE AND ETHICS GO TOGETHER, AS DR. KOSKIE SO ELOQUENTLY ARGUED, THEN HUMAN SUBJECT PROTECTION IS A PROGRESSIVE STEP TOWARDS BETTER SCIENCE AND A MORE RESPECTFUL SOCIETY.

THANK YOU. I WOULD BE PLEASED TO ANSWER ANY QUESTIONS.

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